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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,633	06/20/2003	Russell L. Dedrick	P1747R1D1C1 7177	
9157	7590 09/10/2004		EXAMINER	
GENENTECH, INC.			HADDAD, MAHER M	
1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			ART UNIT	PAPER NUMBER
500111511	, , , , , , , , , , , , , , , , , , , ,		1644	
			DATE MAILED: 09/10/200	4

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
Office Action Summary		Application No.					
		10/600,633	DEDRICK ET AL.				
omoc Aouon cann	,,, y	Examiner	Art Unit				
TI 15411 11/2 DATE 5.11		Maher M. Haddad	1644				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM							
THE MAILING DATE OF THIS CO  - Extensions of time may be available under the after SIX (6) MONTHS from the mailing date  - If the period for reply specified above is less to the information of the period for reply is specified above, the information of the period for reply within the set or extended period for the period for reply within the set or extended period for the period for reply within the set or extended period for the period	DMMUNICATION. e provisions of 37 CFR 1.13 of this communication. than thirty (30) days, a reply maximum statutory period w iod for reply will, by statute, ree months after the mailing	•	nely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133).				
Status							
1) Responsive to communicati	on(s) filed on	<u>.</u> .					
2a) This action is FINAL.	2b)⊠ This	action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) <u>1-32</u> is/are pending	g in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are object	7) Claim(s) is/are objected to.						
8)⊠ Claim(s) <u>1-32</u> are subject to	restriction and/or e	lection requirement.					
Application Papers							
9) The specification is objected	to by the Examiner						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a)□ All b)□ Some * c)□ No	ne of:						
<ol> <li>Certified copies of the priority documents have been received.</li> </ol>							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the In	ternational Bureau	(PCT Rule 17.2(a)).					
* See the attached detailed Offi	ce action for a list o	f the certified copies not received	l.				
Attachment(s)		., <b>C</b>					
Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Interview Summary (PTO-413)  Paper No(s)/Mail Date							
<ol> <li>Notice of Draftsperson's Patent Drawing I Information Disclosure Statement(s) (PTC Paper No(s)/Mail Date</li> </ol>		5) Notice of Informal Part 6) Other:					

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## **DETAILED ACTION**

- 1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-22, drawn to a method for reducing the occurrence of fever, headache, nausea and/or vomiting associated with the administration of a therapeutic compound, and a method for treating an LFA-1 mediated disorder, classified in Class 424, subclass 133.1, 134.1 and 173.1.
  - II. Claim 23, drawn to a method for conditioning a mammal to tolerate high doses of a therapeutic compound; classified in Class 424, subclass 133.1, 134.1, 172.1 and 173.1
  - III. Claims 24-32, drawn to 24-32, drawn to a method for down modulating a cell surface receptor in a cell population in a mammal, classified in Class 424, subclass 133.1, 134.1, 172.1 and 173.1.
- 2. Groups I-III are different methods. A method of reducing, a method of conditioning and a method for down modulating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.
- 3. These inventions are distinct for the reasons given above. Further, even though in this case the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

## Species Election

4. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

If Group I is elected, applicant is required to elect a single specific disorder such as psoriasis, asthma, rheumatoid arthritis, multiple sclerosis, rejection of a transplanted graft or rejection by a transplanted graft recited in claim 16. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Art Unit: 1644

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

5. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

- 6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D. Patent Examiner Technology Center 1600 September 3, 2004

CUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600